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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,592	08/27/2003	Noubar B. Afeyan	COTH-P01-001	7920

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EXAMINER

MEAH, MOHAMMAD Y

ART UNIT PAPER NUMBER

1652

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/650,592	AFEYAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mohammad Meah	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-155 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-155 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The claims 1-155 are pending in the instant office action.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

The inventions are distinct, each from the other because of the following reasons:

Group I. Claims 1-134, drawn to adzymes (fusion proteins comprising catalytic domains and targeting domains), classified in class 435, subclass 226.

Group II. Claims 135-136, drawn to methods of making a medicament, classified in class 424, subclass 94.63.

Group III. Claims 137-138, drawn to methods of treatment of diseases using adzymes, classified in class 424, subclass 94.63.

Group IV. Claims 139-151, drawn to nucleic acids, vectors, host cell and expression of adzymes, classified in class 435, subclass 226.

Group V. Claims 152-154, drawn to methods of designing adzymes, classified in class 435, subclass 23.

Group VI. Claim 155, drawn to operating an adzyme business, classified in class 705, subclass 26.

Inventions in group I and II or III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

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different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case group II methods of making medicament can involve different products (such as different chemical compounds) than that of group I adzymes. Group III methods of treatment of diseases can involve different product (such as different pharmaceuticals) than that of group I and group I product can be used for different process (such as bioassay).

Inventions in group II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions: methods of production of medication (group II) and methods of treatment of diseases (group III) comprise different steps and produce different results.

Inventions of group IV and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of group I can be made by other process than that of group IV such as chemical synthesis.

Inventions in group IV& II; IV& III; IV&V and IV&VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, inventions in group IV are DNA, vectors,

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host cells, involve products that are neither used by method preparation of medicament (group II) or method of treatment (III) or design of adzyme (group V) or running a business (group VI).

Inventions group V and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of group I can be made by other process than group V such as chemical synthesis.

Inventions in group V and group II, III and VI are unrelated. In the instant case the different inventions: methods of production of medication (group II) and methods of treatment of diseases (group III) and method of operating business (group VI) comprise different steps and produce different results than that of group V method of design of adzyme.

Invention in group VI and I, II or III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case running an adzyme business (group VI) comprises unrelated steps to the methods of group II or III and produce different results.

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For each of inventions in group I-VI above, the following restriction is also required under 35 USC 121. Therefore election is required of one of the inventions I-VI and one of the inventions defined below:

Inventions in claims 1-155 comprise an adzyme or methods of making or using an adzyme, wherein said adzyme is a fusion protein comprising catalytic domain and a targeting domain attached via no linker or linker. The catalytic domain is selected from any of a wide variety of species comprising: chemical compound (that catalyze chemical reaction), polypeptide, protease ( MT1, MPP, MMP12, tryptase, MT2-MPP, elastase, MPP7, chemotropism and trypsin), esterase, amidase, lactamase, cellulase, oxidase, oxidoreductase, reductase, transferase, hydrolase, isomerase, ligase, lipase, phospholipase, phosphatase, kinase, sulfatase, lysozyme, glycosidase, nuclease, aldolase, ketolase, lyase, cyclase, reverse transcriptase, hyaluronidase, amylase, cerebrosidase, chitinase that listed in claims 66,117-118; and targeting moiety is selected from any class of a wide variety of species comprising chemicals, polypeptide, polypeptide complex, polyanionic compound, polycationic compound, oligonucleotides,, polysaccharide, lectin, antibody, Fab, scFv, artificial protein, TNF, sp55 of TNFR1, etc.

Each catalytic domain of the fusion proteins encompassed by the instant claims is a patentably distinct protein having a different structure than the other catalytic domains encompassed by the instant claims. Similarly, each specific targeting domain encompassed by the instant claims is a patentably distinct protein having a different structure than the other targeting domains encompassed by the fusion proteins of the instant claims. Each specific linker encompassed by the instant claims is a patentably

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distinct amino acid sequence having a different structure than the other linkers encompassed by the instant claims. N combinations of catalytic domain with N combinations of targeting domain will produce  $N^2$  (such as  $10 \times 10 = 100$ ) patentably distinct adzymes having different structures. Furthermore each specific fusion protein will have distinct functional properties as well. As such each adzyme fusion protein is an independent invention. In view of the enormous number of independent inventions encompassed the examiner has not attempted to exhaustively list each independent invention herein. Applicants are required to identify a specific adzyme fusion protein for examination by electing a specific catalytic domain and a specific targeting domain. Applicants are further required to identify which claims encompass the elected invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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